

ADMINISTRATIVE INFORMATION

Manufacturer Name:

MAST Biosurgery, Inc.
6749 Top Gun Street, Suite C
San Diego, CA 92121

MAR 07 2007

Official Contact:

Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name:

Surgical Mesh, Polymeric

Trade/Proprietary Name:

Surgi-Wrap MAST Tendon Sheet

ESTABLISHMENT REGISTRATION NUMBER

3004661493

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 878.3300, Surgical Mesh are polymeric screens intended to be implanted to reinforce soft tissues. These devices are classified as Class II. Surgical Mesh have been assigned Product Code FTL and FTM.

INTENDED USE

The Surgi-Wrap MAST Tendon Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the tissues.

The Surgi-Wrap MAST Tendon Sheet is also indicated for reinforcement of soft tissues repaired by suture or suture anchors, during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Surgi-Wrap MAST Tendon Sheet is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. The Surgi-Wrap MAST Tendon Sheet reinforces soft tissue and provides a remodelable scaffold that is replaced by the patients own soft tissue.

The device is indicated for open and laparoscopic / endoscopic procedures. Laparoscopic / endoscopic procedures are limited to sizes from 0.02mm – 0.2mm in thickness.

K063648
2/3**DEVICE DESCRIPTION****Design Characteristics**

The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is a resorbable implant in sheet form manufactured from poly (L-lactide-co-D,L-lactide) 70:30 (PLA). The Surgi-Wrap MAST Tendon Sheet can be cut with scissors to the desired shape and size. The Surgi-Wrap MAST Tendon Sheet is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The Surgi-Wrap MAST Tendon Sheet can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which can also serve to fixate the Surgi-Wrap MAST Tendon Sheet and prevent dislocation. The Surgi-Wrap MAST Tendon Sheet may be used in conjunction with various MAST Biosurgery Class I manual instruments (forceps, scissors, clamps, etc.).

The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular surgical procedures. The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is provided in sheets of 25mm x 25mm to 500mm x 500mm and will be provided in other shapes and sizes as needed for particular surgical procedures. The thickness of the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet ranges from 0.02 mm to 1.0 mm according to the region to be treated. The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is provided in solid sheets. The borders of the sheets may be aligned with holes to attach suture material.

Material Composition

The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is fabricated from polylactic acid (PLA).

In Vitro Testing

The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures. Therefore, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. The relatively brief exposure anticipated during the surgical preparation of MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MAST Biosurgery Surgi-Wrap MAST Tendon Sheet. Testing demonstrated that the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is strong enough for the indications for use.

Mechanical testing was performed on the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet which determined the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

In Vivo Testing

Animal studies were conducted to demonstrate safety and efficacy of the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet material. The animal studies demonstrated that the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet materials are safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETING PRODUCT

The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K061473), Integra LifeSciences Tendon Wrap (K053655), TEI Biosciences TissueMend Soft Tissue Repair Matrix, (K060989) and S. Jackson Supra FOIL Smooth Nylon foil Sheets (K973379); Class II medical devices that were cleared for marketing in the United States under K061473, K053655, K060989 and K973379 respectively.

Indications For Use

The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet shares indications for use principles with the predicate devices as all devices are indicated for use in the same surgical procedures involving tendons. Furthermore, the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet shares identical indications for use language with each of the predicate devices.

Design and Materials

The physical designs of the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet and the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K061473), Integra LifeSciences Tendon Wrap (K053655), TEI Biosciences TissueMend Soft Tissue Repair Matrix, (K060989) and S. Jackson Supra FOIL Smooth Nylon foil Sheets (K973379) predicate devices are substantially equivalent as they are all flexible and malleable sheets provided in various sizes that they can be cut to shape intra-operatively and subsequently placed on, under, and around tendon anatomy. The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet and the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K061473), Integra LifeSciences Tendon Wrap (K053655), and TEI Biosciences TissueMend Soft Tissue Repair Matrix, (K060989) predicates all share the common design feature of being bioresorbable. The MAST Biosurgery Surgi-Wrap MAST Tendon Sheet is substantially equivalent to the S. Jackson Supra FOIL Smooth Nylon foil Sheets (K973379) and MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K061473) predicates as they are all thin, semi-rigid sheets provided in sizes ranging from 25mm x 25mm and 500mm x 500mm with various thicknesses ranging from 0.02mm to 1.0mm. The mechanical characteristics of the MAST Biosurgery Surgi-Wrap MAST Tendon Sheet are substantially equivalent to the predicate devices with respect to mechanical characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAST Biosurgery, Inc.
% Mr. Kenneth K. Kleinhenz
Regulatory Affairs
6749 Top Gun Street, Suite C
San Diego, California 92121

MAR 07 2007

Re: K063648

Trade/Device Name: Surgi-Wrap MAST Tendon Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 4, 2006
Received: December 7, 2006

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

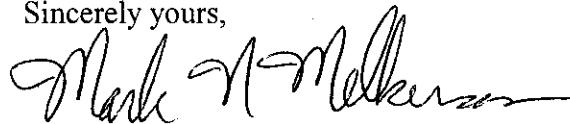
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Kenneth K. Kleinhenz

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063648

Indications for Use

510(k) Number :

Device Name: Surgi-Wrap MAST Tendon Sheet

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR/Office of Device Evaluation (ODE)


(Division Sign-off)

**Division of General, Restorative,
and Neurological Devices**

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510(k) Number K063648